

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-487 /S-003

ADMINISTRATIVE DOCUMENTS
AND
CORRESPONDENCE

ORIGINAL

GlaxoWellcome

July 8, 1996

Ko Yu Lo, Ph.D.
Division of Antiviral Drug Products
Center for Drug Evaluation and Research
Attn: Document Control Room
Office of Drug Evaluation II
Food and Drug Administration
NRC HFD-530
5516 Nicholson Lane
Kensington, MD 20895



BC
NDA SUPPL AMENDMENT
S-002

Re: NDA 20-487: VALTREX[®] (valacyclovir hydrochloride) Caplets for Herpes Zoster Virus
Supplemental Application - Expedited Review Requested : CMC

Dear Dr. Lo:

Reference is made to a telephone conversation of 17 June 1996 between Mr. Leo Lucisano and Dr. Ko-Yu Lo in which Dr. Lo requested additional information to complete an Expedited Review of a Supplement to change the particle size specification for colloidal silicon dioxide (excipient) in VALTREX[®] Caplets. Enclosed are the following:

• []
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•

If you should require any further information, please do not hesitate to contact me at (919) 483-5848. Upon approval of the supplement, the proposed particle size specification and testing instructions for Silicon Dioxide Colloidal will be adopted.

Sincerely,

Leo Lucisano

Leo Lucisano
Assistant Director
Regulatory Affairs

enclosure: 5 pages

Glaxo Wellcome Inc.

Five Moore Drive
Research Triangle Park
North Carolina 27709

Telephone
919 248 2100

REVIEWS COMPLETED	
CSO ACTION:	
<input type="checkbox"/> LETTER	<input type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO
CSO INITIALS	DATE



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date APR 16 1996

NDA No. 20-487

GLAXO WELLCOME INC.
Five Moore Drive
Research Triangle Park, N.C. 27709

Attention: Leo Lucisano
Assistant Director
Regulatory Affairs

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: VALTrex (valacyclovir hydrochloride) Caplets for Herpes Zoster Virus

NDA Number: 20-487

Supplement Number: SCS-003

Date of Supplement: April 9, 1996

Date of Receipt: April 11, 1996

Unless we find the application not acceptable for filing, the filing date will be 60 days from the receipt date above.

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Attention: Document Control, Room 12B-30
5600 Fishers Lane
Rockville, MD 20857

Sincerely yours,

[Signature]
Supervisory Consumer Safety Officer
Division of Anti-Infective Drug Products
Center for Drug Evaluation and Research

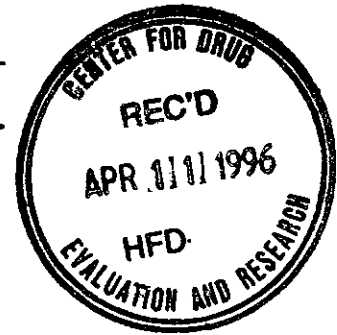
**Appears This Way
On Original**

GlaxoWellcome

ORIGINAL

NDA NO. 20-487 REF. NO. 003

NDA SUPPL FOR SCS



April 9, 1996

David W. Feigal, Jr., M.D., M.P.H., Director
Division of Antiviral Drug Products
Attn: Document Control Room
Food and Drug Administration
Fourth Floor
9201 Corporate Boulevard, HFD-530
Rockville, MD 20850

**Re: NDA 20-487; VALTREX® (valacyclovir hydrochloride) Caplets for Herpes Zoster Virus
Supplemental Application - Expedited Review Requested: CMC**

Dear Dr. Feigal:

Reference is made to a telephone conversation of 13 March 1996, between Mr. Joey Pollock of our firm and Dr. Chi Wan Chen of your Division, regarding a request for Expedited Review of a Supplement to change the particle size specification for colloidal silicon dioxide (excipient) in VALTREX Caplets. Attached please find our justification for this change.

Glaxo certifies that it did not and will not use in any capacity the services of any person debarred under Section 306(a) or (b) of the Generic Drug Enforcement Act of 1992 in connection with this application.

A field copy of this application has been sent to:

Food and Drug Administration
60 Eighth Street, N. E.
Atlanta, GA 30309

If you should require any further information please do not hesitate to contact me at (919) 483-5848.

Sincerely,

Sherry Watson/for

Leo Lucisano
Assistant Director
Regulatory Affairs

REVIEWS COMPLETED	
CSO ACTION:	
<input type="checkbox"/> LETTER	<input type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO
CSO INITIALS	DATE

cc: Dr. Chi Wan Chen (desk copy)
Dr. Ko Yu Lo (desk copy)

Glaxo Wellcome Inc.

Five Moore Drive
Research Triangle Park
North Carolina 27709

Telephone
919 248 2100

020487.5003